Task Force 2: Donor Guidelines

JOHN C. BALDWIN, MD, FACC, CHAIRMAN, JEFFREY L. ANDERSON, MD, FACC, CO-CHAIRMAN, MARK M. BOUCEK, MD, FACC, MICHAEL R. BRISTOW, MD, PHD, FACC, BRUCE JENNINGS, MA, MALCOLM E. RITSCH, JR., JD, NORMAN A. SILVERMAN, MD, FACC

Introduction

Since the introduction of clinical cardiac transplantation in December 1967, the growth in the number of transplant operations has been directly dependent on the identification and procurement of cardiac allograft donors. Heart transplantation was sustained and shown to be successful by Shumway and his colleagues in the Department of Cardiovascular Surgery at Stanford during the 1970s. The success of their program was dependent on the development of brain death criteria, medical criteria for proper donor selection, principles of donor management and technical details of donor procurement and preservation (1). Their pioneering work forms the basis for donor identification and management today, and attention is now properly focused on means of expanding the potential donor supply through extension of criteria for acceptance of donors and through developing strategies to broaden the potential donor pool. While biologic replacement (either allograft or xenograft) promises to be preferable to mechanical replacement of the heart in terms of quality of life for the recipient, the number of patients with end-stage heart failure able to be treated with biologic heart replacement will remain strictly dependent on our ability to identify and procure suitable donor hearts.

Brain Death Criteria

The initial step in donor procurement must be the recognition and declaration of brain death of the donor. Estimates of potential donor availability indicate that 15% to 30% of individuals who could meet brain death criteria are not appropriately identified. Explanations for failure to recruit donors may include these possible physician characteristics: 1) unfamiliarity with brain death criteria; 2) desire to avoid discussing the concept of brain death with the family; 3) perception of a lengthy, "legalistic," complex process for organ donation; 4) lack of comfort with the concept of brain death. Surveys have indicated that the concept of brain death is, in fact, overwhelmingly accepted by physicians in the United States, and all 50 states and the District of Columbia have accepted brain death as a definition of death by statute or judicial decision. Thus, the timely determination of brain death and physicians' difficulty in discussing brain death with families would appear to be the major impediments to appropriate donor identification.

The diagnosis of brain death can be made by the attending physician or consultant using equipment readily available in an intensive care area. Members of the heart transplant team or procurement team do not participate in the brain death determination. One critically important role for the cardiologist is donor evaluation, because the enlarging recipient list has led to the acceptance of extended criteria for suitable donors but concomitantly increased the importance of careful scrutiny of the potential donor heart. This report outlines general criteria for the diagnosis of brain death, which most often can be determined on clinical grounds alone. The specific application of brain death criteria must conform to individual state laws, which may contain minor variations from state to state.

The clinical diagnosis of brain death requires 1) that there be loss of function of the entire brain, including the cortex and brain stem, *and* 2) that the loss of brain function be irreversible. Brain death may, of course, be present in the setting of persistent vital signs because of life support measures. Irreversibility is a key concept in the definition of brain death and implies that the cause is sufficiently well understood to confidently predict the outcome.

The clinical definition for loss of entire brain function includes the following:

1. Loss of cortical function
   a. Presence of deep coma
   b. Lack of spontaneous motor activity (*spinal reflexes may be present even with complete brain death*)
   c. Absence of response to deep painful stimuli
2. Loss of brain stem activity
   a. Absence of respiratory effort (apnea). (*Apnea is demonstrated by preoxygenating the patient with 100% fractional inspiratory oxygen for 10 min before disconnecting the ventilator. After the ventilator is disconnected, oxygen is provided by tracheal cannula at 8 liters/min. The patient is observed for 5 to 10 min to allow carbon dioxide to accumulate and stimulate respiration. If there are no respiratory efforts an arterial blood gas measurement is obtained and the*

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ventilator is reconnected. If the arterial partial pressure of carbon dioxide is >60 mm Hg, the test is considered to be valid and apnea to be present.)

b. Lack of pupillary or corneal reflexes. *(Pupillary constriction in response to a bright light is best demonstrated in a darkened room. The cornea is tested by touching with a cotton swab. Absence of pupillary change in response to light or blinking in response to corneal touch indicates brain stem inactivity.)*

c. Lack of gag or cough reflex, even with tracheal suctioning.

d. Lack of oculocephalic or "doll's eye reflex." *("Doll's eye" test is performed by turning the head from side to side with the head tilted forward 30°. If the eyes passively follow the rotating head without a lag, the oculocephalic reflex is considered absent.)*

e. Lack of ocular-vestibular ("caloric") response. *(Instillation of 10 ml of ice water into the external ear canal should cause deviation of the eyes from the stimulated side. Absent eye movement response indicates lack of oculovestibular response.)*

Irreversibility of loss of brain function requires that:

1. Brain death has a defined etiology and there is no likelihood of recovery.
2. The patient is normothermic, defined as a core temperature >32.5C.
3. Pharmacologic agents capable of central nervous system depression, neuromuscular blockade or disassociative coma are absent or below therapeutic levels.
4. These criteria for loss of brain function persist for a 12- to 24-h observation period. A shorter observation period (6 h) can be used if irreversibility can be confirmed by other means, such as demonstration of lack of cerebral blood flow.

Confirmation of the diagnosis of brain death by a second physician is a prudent precaution and is required by law in some states. Laboratory confirmation, including the documentation of a flat electroencephalogram (EEG), is usually not required provided there is an obvious cause for irreversible brain death and the observation period is sufficient. If there is a question of etiology or irreversibility (e.g., with uncertainty regarding drug overdose), laboratory testing to include cerebral blood flow measurements or an EEG may be required to confirm the diagnosis of brain death. However, it is possible to meet the criteria for brain death in the absence of electrocortical silence on the EEG.

Very young age of the potential donor may also necessitate confirmatory laboratory testing. For premature infants of <32 weeks' gestation, brain death criteria are not well established. For newborn full-term infants an observation period of 72 h has been recommended and should be buttressed by laboratory testing. Some investigators have recommended an even longer period of observation for premature infants. For infants <2 months of age, the recommendations include two EEGs separated by 48 h or a brain blood flow study. For infants between 2 months and 1 year of age, a repeat EEG or a brain blood flow study should be performed 24 h after the first EEG. For children >1 year old, laboratory testing is not required unless there is doubt about the irreversibility of the cause, as in adults. Brain death should be documented in the chart with reference to clinical examination criteria, laboratory testing (if done), as well as determination of irreversibility.

The concept of brain death is accepted by the public at large, as has been confirmed by several studies including "The Presidential Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research: Guidelines for the Determination of Death" (2). Physicians in general also accept the concept of brain death but are generally unfamiliar with its exact application. The criteria for establishing brain death are thorough and specific to protect the individual, and are straightforward so as not to be unduly burdensome on the family or attending physician. It is important for physicians to be familiar with the criteria for brain death so that the option of organ donation can be presented to the family in a timely and unambiguous fashion.

Medical Criteria for Donor Selection

The screening of potential cardiac donors is accomplished in three phases. *Primary screening* is done by organ procurement specialists who work for the nonprofit organ procurement agencies. Information pertinent to all organ donation is obtained initially, including body size, ABO blood type, hepatitis B and human immunodeficiency virus (HIV) serologic data, information on cause of death and clinical course and routine laboratory data. *Secondary screening* is done by cardiac surgeons or cardiologists. Information relevant to cardiac donation includes determination of the circumstances leading to severe brain injury, extent of other (especially thoracic) injuries, the extent of treatment required to sustain an acceptable hemodynamic status, baseline electrocardiogram (ECG), chest X-ray film, arterial blood gas analysis and echocardiogram. The purpose of this secondary screen is to provide enough information to decide whether to implement the *tertiary screen*, which is inspection of the heart by a "harvesting" surgeon.

Because of a profound shortage of cardiac organ donors and high pretransplantation mortality rates of patients listed for heart transplantation, it is clear that donor screening strategy should be liberal. Conversely, because primary graft failure is almost always associated with death of the heart transplant recipient, the screening strategy must identify hearts that will reliably support the circulation in the immediate posttransplantation period.

From the preceding information obtained on the primary and secondary screen, it is possible to devise a system of absolute and relative contraindication to the use of the donor heart for transplantation. However, because the continuing severe shortage of cardiac donors, it is important to emphasize *inclusivity* and thoughtful evaluation and consideration of every potential donor heart.

Absolute contraindications include:

1. HIV positivity (? except in cases of HIV-positive recipients)
2. Death from carbon monoxide poisoning, with blood carboxyhemoglobin level >20%
3. Intractable ventricular arrhythmia
4. Inadequate oxygenation, with arterial saturation <80% on ventilatory support
5. Documented previous myocardial infarction
6. Clinically significant structural heart disease, intracardiac tumor or severe global hypokinesia with ejection fraction <10% as determined by echocardiogram
7. Severe occlusive coronary artery disease on arteriography

Relative contraindications include:

1. Hepatitis B surface antigen positivity (? except in cases of surface antigen positive recipients)
2. Bacterial sepsis
3. Hepatitis C positivity
4. History of metastatic cancer
5. Extensive chest wall trauma with evidence of cardiac contusion by ECG or echocardiography
6. Prolonged hypotension, defined as a systolic blood pressure <60 mm Hg for >6 h
7. Recurrent supraventricular arrhythmia
8. Prolonged need for inotropic support, defined as a dopamine dosage >20 μg/kg per min for >24 h or comparable dosage of other beta-agonist or epinephrine, norepinephrine, or dobutamine for the same period
9. Prolonged resuscitation time after cardiopulmonary arrest, defined as attempted cardiopulmonary resuscitation for >30 min performed within 24 h of organ harvest or multiple episodes of attempted cardiopulmonary resuscitation
10. Severe left ventricular hypertrophy on electrocardiogram or echocardiogram
11. Echocardiogram revealing moderate hypokinesia, which is typically segmental in brain injury, with shortening fraction 10% to 25%
12. Noncritical coronary disease on arteriogram
13. History of carbon monoxide inhalation, with blood carboxyhemoglobin <20%
14. History of intravenous drug abuse

The decision to use a donor with a relative contraindication depends on the recipient's clinical situation, and to some extent on the size relation between the prospective donor and recipient. The pulmonary artery pressures in the recipient also affect the decision when there is mild to moderate myocardial dysfunction in the donor; higher pressures will predictably require a stronger donor heart.

It is recommended that coronary arteriography be performed in male donors >45 years of age and in women donors >50 years of age before the heart is approved for transplantation. If significant risk factors are present, those ages should be lowered by 5 to 10 years. If small amounts of nonionic contrast medium (<40 ml) are used, studies have shown there is no adverse effect on renal function. This is of concern because most donors today provide multiple organs for transplantation, including kidneys.

Because cardiac function declines with age as a result of multiple mechanisms, it is recommended that the donated organ be from someone who is not substantially older than the recipient. For example, the use of a 65-year old heart in a 16-year old patient, unless it is absolutely life-saving, would not be advised because of the limitations on exercise performance inherent in an aged heart. However, the use of a 65-year old heart in a 60- to 70-year old recipient, who will have a more conservative functional capacity requirement, is quite acceptable.

Echocardiograms have proved enormously useful in donor organ screening and should be used routinely to examine cardiac function in the setting of clinical instability or history of high pressor requirement. However, imaging is not easily performed in all patients, particularly those on ventilators. It is recommended that a transesophageal echocardiogram be performed if transthoracic visualization is inadequate.

The final decision to use a heart for organ donation is made by the surgeon at the time of direct inspection or "harvest" (tertiary screening). On occasion, cardiac function will have deteriorated in the interval after an echocardiogram has revealed acceptable cardiac function. Also, the presence of cardiac contusion is best evaluated by direct inspection.

Obtaining Consent

Most potential organ donors are under coroner's jurisdiction because of death resulting from accident, homicide or suicide. Thus, in most cases local coroners must be contacted to obtain permission for recovery of organs and tissue. The Uniform Anatomical Gift Act adopted in 1968 calls for, but does not require, persons >18 years of age to sign a card indicating willingness to donate body parts for transplantation and other medical purposes. In the U.S., the ordinary protocol is to verify consent with the family. When consent has not been indicated with a donor card signature, the family is approached in the same fashion. Consent should be obtained from the next of kin or from a person who has authorized power of attorney. It is important for there to be a consensus among family members, and this aspect should be explored sensitively by the physicians and coordinators involved. The local organ procurement organization should be contacted as soon as declaration of brain death is anticipated.

Families must be approached in a sensitive and caring manner, preferably by a professional coordinator, with sufficient time allowed for their understanding and acceptance of the death of the donor. It is important for the family to

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have an opportunity for privacy during their discussions of these matters. Information given to the family should include examples of how patients benefit from transplantation (without reference to specific potential recipients), and reassurance that no additional medical costs will be incurred by the family because of the donation. In addition, it is important to remind the family that the body will not be disfigured as a result of the organ donation.

Medical Management of the Donor Before Transplantation

Basic principles of cardiac donor management are now well established. After brain death has been declared and the suitability for cardiac allografting has been determined by history, physical examination, electrocardiography and echocardiography, the main goal of donor medical management is to maintain hemodynamic stability. In the intensive care unit, continuous monitoring of intraarterial pressure, central venous pressure and indwelling urinary catheter output is mandatory. Insertion of a Swan-Ganz pulmonary artery catheter is not routinely recommended unless it has been previously placed to assess cardiac performance. Donors have usually had fluids restricted to minimize cerebral edema and are therefore hypovolemic; fluid resuscitation should be initiated with a bolus infusion of 1,000 ml of a balanced salt solution and adequate hydration maintained by hourly infusion of 100 to 150 ml in addition to the past hour's urinary output. Adequate fluid administration should maintain systolic blood pressure >100 mm Hg if the central venous pressure is <10 to 12 mm Hg. Hypotension despite adequate filling pressure is treated with dopamine. The dosage is titrated to maintain systolic performance; however, infusions >7.5 to 10 μg/kg per min should be avoided. Crystalloid rehydration may amplify the effects of previous blood loss, necessitating transfusion of red cells to maintain hematocrit levels above 30%. Sufficient red cell mass is particularly critical for multiple organ donors because the harvesting procedure is of 2 to 4 h duration and results in significant blood loss.

Fluid management after brain death is often complicated by the development of diabetes insipidus due to pituitary nonfunction. Urinary output ≥300 ml/h is a sign of diabetes insipidus and should be treated with infusion of parenteral vasopressin titrated to keep urinary volume <150 ml/h. Hemodynamic lability of the donor can be evidenced by hypertension as well as hypotension. Increased systemic pressure results when vasopressin is used and increased intracranial pressure also causes massive sympathetic discharge with attendant vascular constriction. Sodium nitroprusside is the preferred drug for rapid and effective afterload reduction.

In addition to fluid management, meticulous attention to maintaining normal electrolyte levels, acid-base balance and oxygenation is critical. The large volume of parenteral infusions and urinary output can cause hypernatremia and hypokalemia. Hourly potassium supplementation is usually required. By definition, all donors are ventilator dependent and frequent blood gas analysis allows correction of inadequate oxygenation and alterations in pH. Brain death is also associated with low pressure, neurogenic pulmonary edema. Frequent endotracheal suctioning and positive end-expiratory pressure usually are required. Lack of thermal regulatory control can be overcome by the use of heating blankets or antipyretic agents, as indicated. After blood, sputum and urine cultures are obtained, broad spectrum antibiotic treatment should be initiated.

The hypothetical relation between cardiac dysfunction and depressed circulating levels of free triiodothyronine has prompted several investigators to treat donors with exogenous thyroid hormone supplementation. At present, the efficacy of such therapy is unproved and it *should not* be routinely used.

Donor Cardiectomy

Intraoperative management by the anesthesiologist is an extension of the strict attention to detail required in the intensive care unit. Heart procurement today is most often part of a coordinated effort by several transplant teams whereby the liver, kidneys, lungs and pancreas may also be harvested (3). In regard to timing of explantation, the heart takes priority over the other viscera. Visual inspection and palpation of the heart are the last potential exclusionary steps in determining donor suitability. Palpable thrills over the great vessels, obvious atherosclerotic lesion of epicardial coronary arteries or areas of myocardial contusion should preclude transplantation.

The surgical procedure is performed as follows. The aorta and pulmonary artery are dissected superiorly to the level of the innominate artery and bifurcation, respectively. The superior vena cava is encircled and dissected superiorly to the level of the azygous vein. When the abdominal team has finished their dissection, the patient is heparinized and a cardioplegic cannula placed in the ascending aorta. The superior vena cava is doubly ligated and divided as far cephalad as possible to avoid injury to the sinoatrial node. Simultaneously, the ascending and descending aortas are clamped and the intracoronary infusate is perfused to arrest the heart. The inferior vena cava is divided at the diaphragm to vent the liver perfusate. The right superior pulmonary vein is incised to vent the heart and avoid distension. Copious topical iced saline solution enhances cardiac hypothermia. Cardioplegic solution, 1 to 1.5 liters, is given depending on the rapidity of electromechanical arrest. After infusion, the heart is excised at the pericardial reflections starting with completion of the inferior vena cava incision, then the pulmonary veins and finally division of the aorta and pulmonary arteries at the level of the innominate artery and bifurcation, respectively. The heart is brought to a back table where it is rinsed thoroughly with saline solution. The

atrial septum is inspected and, if a patent foramen ovale is present, it is closed with sutures. The great vessels are separated. Incisions are made connecting the pulmonary veins, and the right atrium is opened from the inferior vena cava toward the atrial appendage to fashion the atrial cuffs for implantation. The heart is then stored in iced saline solution for transport. When the lungs are being harvested, the technique is modified for en bloc removal of the heart and lungs. The heart is then separated from each lung so as to ensure an adequate left atrial cuff for each organ.

Currently, three types of crystalloid cardioplegic formulas are utilized. St. Thomas' solution is a hyperkalemic, extracellular formula that is unmodified from the infusate used with standard cardiac surgical procedures. Stanford solution also utilizes potassium as the chemical cardioplegic agent, but is low in sodium, is acalcemic and has high concentrations of glucose and mannitol. These "standard" formulas provide up to 5 h of safe arrest in cold storage. Because this time period must include preparation after explantation, travel and subsequent implantation, there are strict time restraints on distance for procurement and surgical expediency. To overcome these problems, recent interest has focused on utilizing University of Wisconsin solution for cardiac preservation. This solution is an intracellular formula with several antioxidants, oncotic agents and metabolic additives that has transformed liver transplantation and allowed prolonged ischemic times. Although experimental evidence suggests that University of Wisconsin solution can increase the safe ischemic time, initial clinical studies have only reflected effective preservation for the 4- to 5-h time limit currently constraining alternative flush and storage modalities.

Means of Increasing Donor Supply

The number of centers performing heart transplantation has increased dramatically in the 1980s, from 12 centers in 1983 to 131 in 1987. In 1988, a total of 1,529 heart transplantations were performed at 109 hospitals. Nonetheless, the potential demand for heart transplantation is far from being met by our health care system. In 1988, 900 patients remained on waiting lists, three times the number awaiting a heart transplant in 1986. The General Accounting Office estimates that in 1988 >500 people died while waiting for a heart. In 1989 nearly 2,000 people on organ transplant waiting lists died. Moreover, while patient need and demand are not being met, our organizational capacity is not being used in an optimal way. Ninety-one of 131 programs reported in 1988 that they had performed <12 transplant procedures.

One obvious response to this situation is to attempt to increase the supply of donor hearts available. Legal changes (such as presumed consent laws) and more support for public education on the issue could facilitate the organ donation consent process. New communication technologies and sharing networks can be utilized to ensure that the available supply of organs is used most efficiently (and fairly) so that organs are not wasted. These kinds of structural changes can help to establish credibility and trust in the organ procurement and transplant system, and this, in turn, should help to overcome some of the psychologic barriers to donation.

Attempts to increase the supply of donor hearts fall into two basic categories. One has to do with how we define the pool of "acceptable" donors (or, alternatively phrased, acceptable organs). The second has to do with how we appeal to and persuade those (or their surrogates) who fall within the pool to agree to donate their heart for transplantation.

A. Broadening the Pool

1. Advances in immunosuppressant drug technology and other ways to circumvent the effects of biologic incompatibility have the effect of increasing the pool of usable organs. Donor criteria can be broadened, but this should only be done in the context of carefully controlled prospective studies using donors previously characterized as "high risk." Ethical issues include definition of acceptable risk and informed consent for recipients.

2. A second important aspect of increasing the supply pool involves the use of anencephalic infants as organ donors. This topic is given added force by the fact that there is a disproportionate shortage of donor hearts for neonatal transplant recipients. The number of anencephalic births is large enough to offset what will otherwise probably be a continuing undersupply of hearts suitable for neonatal transplants.

3. A third way of increasing the pool of usable hearts is to turn to nonhuman donors. Discordant xenografts, possibly using pigs, may be possible with transgenic techniques and will facilitate large numbers of transplants. Xenografting is the most compelling long-term solution to the cardiac donor problem, as is discussed by Task Force 6.

B. Increasing Consent

In addition to broadening the pool, the other method of increasing the supply of organs is to increase the frequency of consent among those already within the pool. Several policy strategies fall within this approach.

1. **Financial incentives.** The offering of financial incentives for organ donation is a controversial potential means of increasing organ donation. Proponents of this approach recognize the immediate objection that it violates long-established public policy against the commercial traffic in body parts. Building the incentive into something like an insurance type death benefit to the person's estate or making it an in-kind benefit for designated survivors are possible ways of circumventing this problem. Other problems with this scheme are that it would contaminate the informed consent process, and would create a conflict of interest

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dynamic in family consent. Recent surveys also indicate that it is opposed by health care professionals, such as neurosurgeons, who might be even less willing than they now are to raise the issue of donation with families. Hence, it has been suggested that a policy of financial incentives could backfire, and lead to a net reduction of available organs.

2. From required request to presumed consent laws. In recent years one cause of low donation rates has been thought to be the unwillingness of health care professionals to approach family members soon after death to request consent for organ donation. Signed donor cards are rare or rarely found; in any case, there is a universal reluctance to take organs even when such a card is found with the deceased unless the consent of the next of kin is also obtained. The passage of laws and regulations requiring hospitals to request consent for donation have been one response.

When these measures have not produced the desired results, the next logical move is to go to a system of "presumed consent" in which the deceased person is presumed to consent to donation unless that person, or the family, takes active steps to object. Two lines of argument support this approach. One is that the majority of people do, in fact, agree with organ donation but have not, or do not wish to, actively contemplate it in advance. Under presumed consent, the "silent consenters" will not be lost as they are in the present system, which is an ostensible required request system in which the active burden of consent still lies on the donor family. The second line of argument supporting presumed consent is the notion that donor organs are properly seen as a social or communal resource. Communal symbolism and perhaps even communal bond are strengthened by reversing the presumption about donation. It is highly selfish and individualistic, so the argument goes, to presume that individuals *do not* wish to donate unless they actively say they do. In Austria, where presumed consent is practiced, the rate of recovery of cadaveric kidneys is almost double that of the U. S. During 1990, there were 19 donors per million population in the U. S. and some 30.7 donors per million in Austria (4).

Recommendations

The Task Force recommends that the medical community work toward the following goals:

1. Standardization of donor management and encouragement of education of critical care specialists in donor management. It is suggested that the American College of Cardiology, the American College of Chest Physicians and the Society of Critical Care Medicine form an ad hoc committee to explore the development of specific training in donor management for critical care physicians and the formal incorporation of these physicians into the procurement process

2. Emphasis in public education regarding the success of cardiac transplantation and the benefits of presumed consent laws

3. Enactment of presumed consent legislation

4. Encouragement of retrospective and prospective studies of donor criteria as they relate to outcome

5. Improvement in organ procurement agency efficiency through mechanisms such as the national death survey by the Agency for Health Care Policy and Research. Establishment of organ procurement organization performance standards for adult and pediatric recovery. Required distribution of organ procurement organization performance data, such as that now compiled by the Association of Organ Procurement Organizations

6. Expansion of the donor pool
   a. Expansion of criteria based on Recommendation 4
   b. Recognition that anencephaly represents a unique category of brain death, which warrants serious evaluation
   c. Research into potentially reversible cardiac dysfunction that is related to brain injury
   d. Encouragement of coroners and district attorneys to facilitate organ donation

7. Encouragement of participation by on-site cardiologists in donor evaluation, including performance of echocardiography and coronary arteriography when indicated

8. Advocacy for increased participation by transplant cardiologists in the governance of organ procurement agencies

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